UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: BeWanda Alexander

From: Clayton Myers, Entomologist **Date**: August 26, 2011 8/26/11

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode:	387325
Decision no.:	445240
Submission no:	890357
Action code:	R310
Product Name:	Ortho ZB FAK
EPA Reg. No or File Symbol:	239-ETRU
Formulation Type:	Broadcast Granules

Ingredients statement from the label with PC codes included: Bifenthrin, 0.20%, PC: 128825; Zeta-Cypermethrin, 0.05%, PC: 129064

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m^2 or mg/cm^2 as appropriate): Broadcast: 0.125-0.50 lbs ai/acre.

I. Action Requested: Data was submitted to support additional claims on a new product.

II. Background: The registrant seeks to register a bifenthrin/zeta-cypermethrin combo product that is identical in ai composition to an already registered product from FMC (279-3344). The registrant is citing-all for efficacy claims and wishes to have all the claims present on the cited label. The registrant also proposes some additional speed of kill claims against fire ants, that are associated with the carrier in this new product. The registrant has submitted 2 efficacy studies for review to support these additional claims.

III. MRID Summaries: (Primary Reviews attached)

a. MRID 48387492

(1) Non-GLP

(2) Field studies were conducted to demonstrate the killing and control efficacy of the product against imported fire ant mounds. Studies were conducted at 3 sites (TX, FL, GA) using mixed stages wild populations of *Solenopsis invicta*. Ant mounds were scouted 24 prior to the study to confirm activity. 3 treatments were applied: a bifenthrin/zeta-cypermethrin combo product, a zeta-cypermethrin product, and an untreated control. Treatments were applied to the mound according to label directions in a 3 ft. radius around the mound, with 3 replicates per treatment. Ant activity was assessed at various time periods after treatment, using a qualitative efficacy rubric, with a rating <1 equivalent to >90% control.

(3) Authors conclude that efficacy is supported for these pests and data demonstrate that the product kills at the efficacy threshold (i.e., <1) within 15 minutes at all 3 sites. The primary reviewer notes that the rates applied to mounds exceed those on the label for broadcast applications. However, the rate is consistent with the amount of product applied directly to mounds, according to the label directions for spot treatments directly onto mounds.

(4) The study is acceptable to support 15 minute killing claims against fire ants for applications of

½ cup product directly onto ant mounds and a 3ft. radius around the mound. This claim is not applicable to broadcast treatments of 100 to 200 lbs/acre.

b. MRID 48387401

(1) Non-GLP

(2) A laboratory study was conducted to demonstrate the physical attributes of Dolomitic limestone pellets compared to peanut hulls when exposed to moisture.Fifty grams of peanut hull and DG Lite granules were placed on paper towels side by side in a foil container and the water was applied using a pull trigger sprayer. Photographs were taken at various time intervals to demonstrate differences between the 2 carriers.

(3) Time release photography show that the DG-lite dissolves more rapidly than peanut hulls. Primary reviewer determined the study was "acceptable" and demonstrates the effectiveness of the DG lite granule

(4) The study is supplemental information, showing that the DG-lite granule dissolves faster than peanut hulls.

IV. RECOMMENDATIONS:

(1) Labeling:

(a) What pests and site/pest combinations may be added as follows to the label based on the submitted or cited data?

15 minute killing claims against ants are acceptable, but only for direct treatment of mounds with spot applications of ½ cup of product per mound.

(b) What pests and site/pest combinations must be removed from the label?

Ant claims must be qualified to exclude Carpenter and Pharaoh Ants, as was done on the cited product 279-3344. This must be done throughout the label

Also, 6 month residual claims against fire ants for rates below 0.5 lbs ai/acre must be removed from the label. At the labeled rate of 0.25 lbs ai/acre, only a 4 month duration of control is supported. The registrant has 2 options to resolve this issue. Either the 6 month claim for fire ants must be revised down to 4 months, or the minimum broadcast rate for treatment of fire ants must be increased to 0.5 lbs ai/acre (200 lbs product per acre, 4.6 lbs/1000 square ft.)

(c) List changes to the directions for use:

The section entitled Spot Treatments; Mound Ant Treatment, including Fire Ants must be modified to include the disclaimer that the fifteen minute efficacy claims only applies to mounds treated directly, at the rates specified. (i.e., the speed of kill claim does not apply to broadcast treatments). Footnote as follows: "Ortho ZB FAK will provide control of ant mounts within 15 minutes*" "*only for direct spot treatment of mounds at the rate of ½ cup per mound. Does not apply to area-wide broadcast treatments." The claim must also exclude Carpenter and Pharaoh Ants.

(d) List changes to the optional marketing claims:

Additional marketing claims for killing in 15 minutes (under Speed and Combo sections on page 10) must be similarly qualified as shown above. These speed claims may only be associated with the direct mound spot treatments. Ant claims must also be qualified to exclude Carpenter and Pharaoh Ants.

All 6 month residual claims against fire ants and an mounds must be modified as discussed above, and also qualified to exclude Carpenter and Pharaoh Ants.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID: 483874-01; Doskocil, J.P., DG-Lite a rapid release granule technology, June 27, 2010.

Overview, Definitions, and General Considerations (810.1000)

Product Name: ORTHO ZB FAK
EPA Reg. No. or File Symbol: 239-ETRU
Decision number: 445240
DP number: 387325

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-06

Primary Reviewer:
Robert Ross, M.S.

Signature: Robert H. Ross
Date: JUL 25 2011

Secondary Reviewer:
Gene Burgess, Ph.D.

Signature: for Gene Burgess
Date: JUL 25 2011

Program Manager:
Robert Ross, M.S.

Signature: Robert H. Ross
Date: JUL 25 2011

Quality Assurance:
Jennifer Goldberg, B.S,

Signature: Jennifer Goldberg
Date: JUL 25 2011

RECOMMENDED CLASSIFICATION: **Acceptable**

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE [810.1000]
MRID:	**483874-01; Doskocol, J.P., DG-Lite a rapid release granule technology, June 27, 2010.**
DP BARCODE:	387325
DECISION NO:	445240
SUBMISSION NO:	890357
SPONSOR:	The Scotts Company LLC, 14111 Scottslawn Road, Marysville, OH 43041
TESTING FACILITY:	The Scotts Company LLC, 14111 Scottslawn Road, Marysville, OH 43041
STUDY DIRECTOR:	Rami K. Soufi, Ph.D.
SUBMITTER:	Jane Rothwell, Analyst, Federal Registrations, The Scotts Company
STUDY COMPLETED:	27/06/2010
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	Not conducted under Good Laboratory Practice Standards
TEST MATERIAL:	PRODUCT NAME: DG-Lite EPA REGISTRATION NUMBER OR FILE SYMBOL: 239-ETRU ORTHO ZB FAK ACTIVE INGREDIENT NAME: NA CHEMICALNAME: NA A.I. %: NA PC CODE: 128825, 129064 CAS NO.: NA FORMULATION TYPE: NA

PRODUCT APPLICATION RATE(S) g/m^2: NA
ACTIVE INGREDIENT APPLICATION RATE(S)g/m^2: NA

PROPOSED LABEL MARKETING CLAIMS:

None

EPA REQUESTS:

[EPA WILL ADD DIRECTIVES HERE]

STUDY REVIEW

Study Number/Title: (if more than one study is provided in the MRID)

Purpose: To demonstrate the physical attributes of Dolomitic limestone pellets compared to peanut hull when exposed to moisture.

MATERIALS AND METHODS

Test Location : NA

Test Material(s): Dolomitic limestone pellets. The reviewer does not know if is it the same as the EPA product or file symbol.

Test Species Name, Life Stage, Sex and Age: NA

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted:

Fifty grams of peanut hull and DG Lite granules were placed on paper towels side by side in a foil container and the water was applied using a pull trigger sprayer. Photographs were taken at increasing time intervals up to 3 hours.

List the treatments including untreated control (express application rate as g/m^2): NA

Number of replicates per treatment: NA

Number of individuals per replicate: NA

Length of exposure to treatment (time in seconds, minutes or hours): NA

Experimental conditions (state relative humidity, temperature, and photoperiod): NA

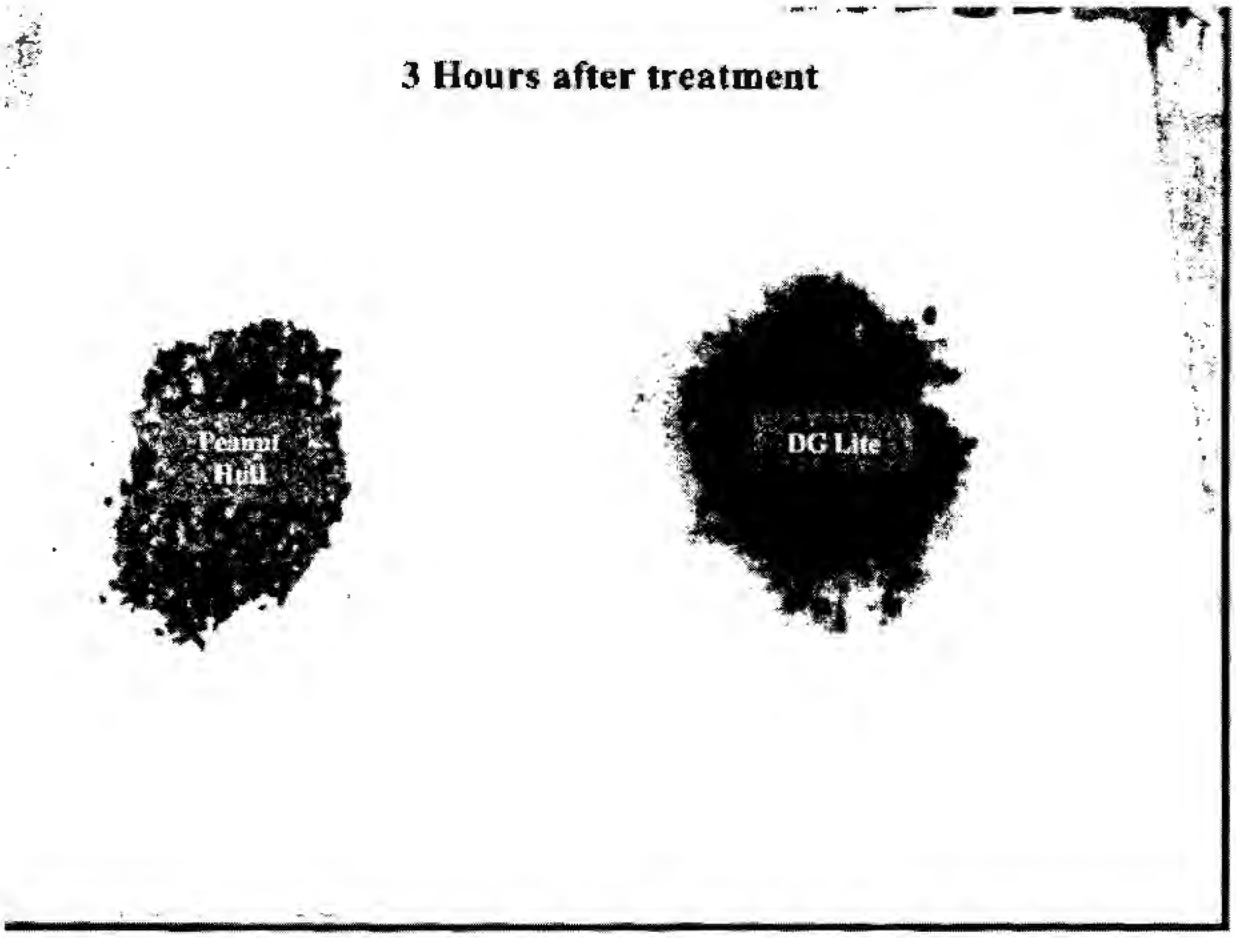
State data or endpoints that were to be collected/recorded: The effectiveness of the dolomitic limestone granules as a carrier compared to peanut hull (50 grams of each) following exposure to moisture using a pull trigger sprayer.

Were the data analyzed? If so, what statistical analyses were performed?

NA

RESULTS

As shown in the figure below, at 3 hours the DG-Lite granule has broken apart to a greater extent than peanut hull. Figures were also provided at 15 seconds and 30 minutes following treatment with water demonstrating the same results.



Study Authors Conclusions

The author states that the DG-Lite granule breaks apart more rapidly than peanut hull after moisture is applied.

Reviewers Conclusions

The time release photography shows that DG-Lite dissolves more rapidly than peanut hull.

Reviewer Recommendations

Study is acceptable and demonstrates the effectiveness of the DG Lite granule.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID: 483874-02; Doskocil, J.P., Speed of fire ant control with a granule formulation containing 0.05% zeta-cypermethrin and 0.20% bifenthrin, November 15, 2010.

Soil Treatments for Imported Fire Ants (810.3100)

Product Name: Ortho ZB FAK
EPA Reg. No. or File Symbol: 239-ETRU
Decision number: 445240
DP number: 387325

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-06

Primary Reviewer:
Robert Ross, M.S.

Signature: Robert M. Ross
Date: JUL 25 2011

Secondary Reviewer:
Gene Burgess, Ph.D.

Signature: Gale Burgess
Date: JUL 25 2011

Program Manager:
Robert Ross, M.S.

Signature: Robert M. Ross
Date: JUL 25 2011

Quality Assurance:
Jennifer, Goldberg, B.S.

Signature: Jennifer Goldberg
Date: JUL 25 2011

RECOMMENDED CLASSIFICATION: **Unacceptable**

Disclaimer

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DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE [810.3100]
MRID:	**483874-02; Doskocil, J.P., Speed of fire ant control with a granule formulation containing 0.05% zeta-cypermethrin and 0.20% bifenthrin, November 15, 2010.**
DP BARCODE:	387325
DECISION NO:	445240
SUBMISSION NO:	890357
SPONSOR:	The Scotts Company LLC, 14111 Scottslawn Road, Marysville, OH 43041
TESTING FACILITY:	The Scotts Company LLC, 14111 Scottslawn Road, Marysville, OH 43041
STUDY DIRECTOR:	Rami K. Soufi, Ph.D.
SUBMITTER:	Jane Rothwell, Analyst, Federal Registrations, The Scotts Company
STUDY COMPLETED:	15/11/2010
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	Not conducted under Good Laboratory Practice Standards
TEST MATERIAL:	PRODUCT NAME: Ortho ZB FAK EPA REGISTRATION NUMBER OR FILE SYMBOL: 239-ETRU ACTIVE INGREDIENT NAME: zeta-cypermethrin and bifenthrin CHEMICALNAME: zeta-cypermethrin and bifenthrin A.I. %: zeta-cypermethrin (0.05%) and bifenthrin (0.20%) PC CODE: 128825, 129064 CAS NO.: zeta-cypermethrin (52315-07-8) and bifenthrin (82657-04-3)

FORMULATION TYPE: Granule
PRODUCT APPLICATION RATE(S) g/m^2: 100 to 200 lbs/acre (11.2 to 22.4 g/m^2, reviewer calculated)
ACTIVE INGREDIENT APPLICATION RATE(S)g/m^2: 0.25 to 0.50 lbs/acre (0.028 to 0.056 g/m^2, reviewer calculated)

PROPOSED LABEL MARKETING CLAIMS: 6 months residual activity with application of 125 lbs/acre

EPA REQUESTS:

[EPA WILL ADD DIRECTIVES HERE]

STUDY REVIEW

Study Number/Title: (if more than one study is provided in the MRID)

Purpose: To document the speed of fire ant control with the use of zeta-cypermethrin (0.05%) and bifenthrin (0.20%) granule formulation.

MATERIALS AND METHODS

Test Location : Marlin, Texas; Apopka, Florida; and Sparks, Georgia

Test Material(s): zeta-cypermethrin (0.05%) and bifenthrin (0.20%) granule formulation which match the label. Bifenthrin (0.20%) was applied alone in a separate test. The reviewer does not know if is it the same as the EPA product or file symbol.

Test Species Name, Life Stage, Sex and Age: Mixed stages of Red Imported Fire Ant, *Solenposis invicta*

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted:

Fire ant mounds were scouted 24 hours prior to treatment and probed to confirm activity. At treatment 95 g of test material was applied directly to mound and to a 3 ft radius around the mound. Two gallons of water was applied to the mound and area around the mound with sufficient force to break the top of the mound.

List the treatments including untreated control (express application rate as g/m^2): 95 g of ORTHO ZB FAK [36.5 g/m^2, based on application to 2.6 m^2 of mound and surrounding area (3 ft

radius from center of mound)]; 95 g of product containing bifenthrin alone (0.20%) [36.5 g/m^2 based on application to 2.6 m^2 of mound and surrounding area (3 ft radius from center of mound)].

Number of replicates per treatment: Three

Number of individuals per replicate: Applied to fire ant mounds

Length of exposure to treatment (time in seconds, minutes or hours): Thirty days

Experimental conditions (state relative humidity, temperature, and photoperiod): Temperature at Marlin, TX site ranged from 56 to 77°F; one application. No other details available.

State data or endpoints that were to be collected/recorded: Fire ant activity and movement at each of the three sites was monitored up to 30 days following a single application to 30 mounds/site (3 replicates of 10 mounds) for a total of 30 data points at each time evaluated (1, 2, 3, 4, 5, 10, 15, 30, 45, and 60 minutes with reevaluation at 30 days). Activity and movement were determined by the following efficacy rubric:

Efficacy Rubric

0 – Complete ant /mound control; no activity or movement observed; all visible ants in the treated area dead.
1 – Acceptable control; ant activity and movement observed; < 10% of ants in treated area alive but all exhibiting signs of morbidity and/or are moribund; 90%+ of ants are dead.
2 – Significant reduction in ant activity and movement observed; < 30% of ants in treated area alive but all exhibiting signs of morbidity and/or are moribund; 70-90% of ants are dead.
3 – Moderate reduction in ant activity and movement; ~ 50% of ants in treated area exhibiting signs of mortality or morbidity; 50-70% of ants are dead.
4 – Minimal reduction in ant activity and movement; < 30% of all ants in treated area exhibit signs of mortality or morbidity.
5 – No visible reduction in ant activity and movement; < 10% of all ants in treated area exhibit signs of mortality or morbidity.

Were the data analyzed? If so, what statistical analyses were performed?

P=.05, Student-Newman-Keuls

RESULTS

As the following tables indicate, excellent control of the fire ants was achieved in 15 minutes or less in all sites and within 4 minutes at the Marlin, TX site with bifenthrin + zeta-cypermethrin, and in general control was achieved faster than with bifenthrin alone. The reviewer found the raw data in Appendix A of the report to be somewhat confusing with no individual mound data presented for the Sparks, GA site and the lack of uniformity in data presentation between the three sites. The data for Marlin, TX was presented in the greatest detail with results for all treated mounds provided. The data in Table 3 can be found on Appendix page 23, but this data appears to be that of the currently registered product (F6133; Reg. No. 279-3344) and thus its comparison to the new product would not be appropriate. In addition, from the data presented on Appendix page 23, it cannot be determined that the data is from field trials in Sparks, GA.

Table 1: Results of field trial conducted in Apopka, FL. Values are defined by the rubric stated in the methods section, < 1 ~ 90% control. Values followed by a different letter are statistically significant, Student-Newman-Keuls at P=0.05

Treatment	Evaluation Time in Minutes										30 DAT
	1	2	3	4	5	10	15	30	45	60	
Bifenthrin + Zeta-Cypermethrin	4.8 b	4.6 c	3.6 b	3.3 c	2.8 c	1.6 b	0.8 c	0.5 c	0.5 c	0.5 b	0.0 b
Bifenthrin	5.0 a	4.7 b	4.2 ab	3.8 b	3.2 b	2.0 b	1.3 b	1.4 b	1.2 b	0.9 b	0.0 b
Control	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a

Table 2: Results of field trial conducted in Marlin, TX. Values are defined by the rubric stated in the methods section, < 1 ~ 90% control. Values followed by a different letter are statistically significant, Student-Newman-Keuls at P=0.05

Treatment	Evaluation Time in Minutes										30 DAT
	1	2	3	4	5	10	15	30	45	60	
Bifenthrin + Zeta-Cypermethrin	2.9 c	1.9 c	1.1 c	0.6 c	0.3 c	0.0 c	0.0 b	0.0 b	0.0 b	0.0 b	0.0 b
Bifenthrin	3.7 b	3.3 b	2.9 b	2.5 b	2.1 b	0.4 b	0.0 b	0.0 b	0.0 b	0.0 b	0.0 b
Control	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	4.0 a

Table 3: Results of field trial conducted in Sparks, GA. Values are defined by the rubric stated in the methods section, < 1 ~ 90% control. Values followed by a different letter are statistically significant, Student-Newman-Keuls at P=0.05

Treatment	Evaluation Time in Minutes										30 DAT
	1	2	3	4	5	10	15	30	45	60	
Bifenthrin + Zeta-Cypermethrin	3.3 b	2.6 c	2.2 c	1.7 c	1.4 c	0.5 c	0.4 b	0.3 b	0.1 b	0.1 b	0.0 b
Bifenthrin	3.9 b	3.5 b	3.0 b	2.7 b	2.1 b	1.0 b	0.5 b	0.3 b	0.2 b	0.2 b	0.0 b
Control	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a	5.0 a

Study Author's Conclusions

Bifenthrin + zeta-cypermethrin achieved excellent control of the fire ant mounds within 15 minutes at all three field locations and control was maintained for 30 days.

Reviewer's Conclusions

The reviewer agrees with the study author's conclusions, but some issues were identified (see reviewer recommendations). The data were not expressed in such a manner for application of Abbott's Formula.

Reviewer Recommendations

Based on the reviewer's calculations, the amount of product applied in the Florida and Texas field trials (36.5 g/m^2) is greater than the range indicated for fire ants on the label (100 to 200 lbs/acre or 11.2 to 22.4 g/m^2). Based on this and the use of Spark's Georgia data for product F6133 which used 65 g of product instead of 95 g, as for the other two sites, this study is unacceptable. The submitter should provide data on the new product for Sparks, GA and provide justification for use of greater than label amounts.